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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/754,456	01/09/2004	Kary B. Mullis	13139-0104 (13721.105006)	7994
20786	7590	04/01/2008	EXAMINER	
KING & SPALDING LLP				
1180 PEACHTREE STREET				
ATLANTA, GA 30309-3521				
			ART UNIT	PAPER NUMBER
			1644	
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			04/01/2008	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Office Action Summary****Application No.**

10/754,456

**Applicant(s)**

MULLIS, KARY B.

**Examiner**

David A. Saunders

**Art Unit**

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11/1/07 & 2/19/08.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-4, 7, 13-18 and 22-36 is/are pending in the application.
- 4a) Of the above claim(s) 1-4, 7, 13-18 and 22-31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 32-34 is/are rejected.
- 7) ☒ Claim(s) 35 and 36 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

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#### **AMENDMENT ENTRY**

Amendment of 2/19/08 has been entered. Claims 1-4, 7, 13-18 and 22-36 are pending. Claims 32-36 are under examination.

#### **RESPONSE TO ELECTION/RESTRICTION**

Applicant's election without traverse of Group II (claims 32-36) in the reply filed on 2/19/08 is acknowledged. Claims 33-34 are currently assumed to be part of Group II, even though claim 33 is recited as depending from claim 3. It is considered that dependency from claim 32 was intended. Accordingly, Claims 33-34 will be examined on the merits with this assumption.

Applicant's election of humoral immunity as the pre-existing species of immunity and of viruses as the target is acknowledged. The examiner shall expand the search in this or future actions, should no art be found against the elected combination of species.

#### **CORRECTIONS REGARDING PREVIOUS OFFICE ACTION**

The restriction mailed 1/17/08 included two versions of pages 4-6. The first pages numbered 4-6 should be ignored.

#### **OBJECTION(S) TO CLAIMS**

Claim 32 is objected to under 37 CFR 1.75(i), as being of improper form for failing to indent each recited element of the immunity linker molecule.

Claim 33 is objected to because of the following informalities: In claim 32, line 1 "3" should read as -32-. Appropriate correction is required.

Claim 33 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. In claim 33 the limitation

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that the "first binding site binds to a pre-existing immune response component" has been recited in base claim 32.

#### **REJECTION(S) UNDER 35 USC 112, SECOND PARAGRAPH**

Claim 34 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 34, line 2 "an antibody to anti-alpha galactosyl epitope" makes no sense. It is believed that applicant intended to recite --an antibody to an alpha galactosyl epitope--.

#### **REJECTION(S) UNDER 35 USC 112, FIRST PARAGRAPH**

Claim 34 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 34 recites new matter.

In claim 34, line 2 "an antibody to anti-alpha galactosyl epitope" makes no sense, unless it is read to mean that the preexisting immune response component is an anti-idiotypic antibody, which is directed against the idiotypic of a pre-existing antibody directed against an alpha galactosyl epitope. Since no pre-existing anti-idiotypic antibodies have been disclosed anywhere in the originally filed disclosure, claim 34 can be read as containing new matter.

#### **DOUBLE PATENTING**

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated

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by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 32-33 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3, 7 and 15-16 of copending Application No. 11/606,564. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are drawn to immunity linker molecules that have both first and second binding sites which are aptamers. The copending claims are broader in terms of the nature of the first site; however, the copending claims clearly encompass the case in which both the first and second binding sites are aptamers (e.g. claim 7).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

## ART OF INTEREST

Low et al (cited in action mailed 6/1/07) teach ligand-immunogen conjugates. In one embodiment, Low et al disclose that a ligand-immunogen conjugate for treating tumors can have a tumor-specific aptamer (col. 8, line 8). Thus Low et al teach a composition that would correspond to applicant's immunity linker molecule for the case in which second binding site is an aptamer that binds to tumor cells as a target.

The art made of record and not relied upon is considered pertinent to applicant's disclosure.

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Epstein et al (2004/0253679, cited on PTO-892) teach a bispecific aptamer that binds to PDGF-B and VEGF ([0182]-[0185] and Ex 11). They also teach that one can provide a targeting aptamer in conjunction with an immunostimulatory nucleic acid sequence ([0186]-[0194] and Ex 12). The immunostimulatory sequence is not an aptamer.

Burke et al (5,637,459, cited on PTO-892) disclose chimeric/multispecific aptamers which have two or more aptamers with different binding functions. Burke et al disclose nothing about immunization, active or passive.

Blesecker et al (5,683,867, cited on PTO-892) teach "blended" nucleic acid ligands, which have an aptamer binding site and a non-nucleic acid binding site. Blesecker et al disclose nothing about immunization, active or passive.

## CONTACTS

Any inquiry concerning this communication from the examiner should be directed to David A. Saunders, whose telephone number is 571-272-0849. The examiner can normally be reached on Mon.-Thu. from 8:00 am to 5:30 pm and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen O'Hara, can be reached on 571-272-0878. The fax phone number for the organization where this application is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Typed 3/26/08 DAS

/David A Saunders/

Primary Examiner, Art Unit 1644

